

## REMARKS

Claims 32-48 and 57 are pending in the application. Applicants request that this amendment be entered and the application reconsidered in view thereof.

Claims 36, 37, 41, 46 and 47 have been withdrawn by the Examiner as being drawn to a nonelected species. Applicants have cancelled claims 46 and 47, but respectfully traverse the withdrawal of claims 36, 37 and 41. Initially, Applicants note that the election made in the Response filed on October 15, 2002 of the aldehyde species as the acid derivative was made in error and that the actual species intended to be elected was anhydride. In fact, examples 1-4 and 7-12 all are drawn to species utilizing succinic anhydride as the acid derivative. Accordingly, Applicants respectfully request that claims 36, 37 and 41 be considered at this time.

Claims 32-35, 38-40, 42-45 and 57 are rejected under 35 U.S.C. 112, second paragraph.

The Office Action states, "Effective amount is not specified as to what effective for, in terms of desired projection." Applicants have amended claim 1 to indicate that the composition comprises a therapeutically effective amount of a therapeutic agent. Support for the amendment is found at page 11, line 17 thru page 14, line 17. Various therapeutic agents are identified for use in compositions of the present invention at page 11, line 24-page 12, line 22. Various forms of delivery of the therapeutic agents also are discussed at page 12, lines 24-27. Typical therapeutically effective amounts of such agents are discussed at page 13, lines 10-15. Other guidance with respect to the relative amounts of therapeutic agents and waxes of the present invention is provided at page 13, line 16-page 14, line 17. Applicants respectfully submit that in view of all of the guidance provided as indicated above, one skilled in the art would understand the term "therapeutically effective amount" to mean that amount which provides the therapeutic affect being sought by administration of a particular therapeutic agent, in a particular form of administration. Applicants further note US 5,670,478 (Stuchlik et al), cited by the Examiner in the continuation-in-part application claiming priority to the instant application, specifically in the Background Art at col. 2, ll 4-56. As clearly stated therein, "Effective immunosuppressive treatment requires keeping a certain level of

cyclosporin in blood and maintaining the level in a certain range. The range required is always specific depending upon therapeutic goal.” Stuchlik refers to “therapeutically suitable concentrations.” Applicants respectfully submit that this is further evidence that one skilled in the art would understand the term “therapeutically effective amount”.

The Office Action states, “the derivatives should be identified, as the examiner fails to find limitation of any particular form.” Applicants respectfully disagree. Applicants respectfully submit that the amount of acid moiety is not determinative as to whether or not a compound is considered a “derivative” of a particular acid. At page 6, lines 10-20, polybasic acids are said to include natural multifunctional carboxylic acids. Exemplary polybasic acids are noted therein, without limitation to additional polybasic acids that may be used in compositions of the present invention. In addition, general chemical classes of derivatives of such acids also are noted. Exemplary derivatives include, without limitation, anhydrides, esters, activated esters and halides. Additional guidance is provided in the examples of the specification. Applicants respectfully submit that one skilled in the art would readily understand “acid derivative” in context of Applicants’ specification.

Regarding claim 38, Applicants, note that there is no typographical error with respect to the range of molecular weight. It is not clear to Applicants if a rejection is being made to claim 38 with respect to molecular weight. Applicants respectfully submit that waxes used in the present invention could have a molecular weight of about 100,000 g/mole and a melting point of less than about 70°C, depending on the particular wax composition.

The Office Action states, “other diols renders claim 43 indefinite.” Applicants have amended claim 43 to delete “other diols”.

Based on all of the foregoing, Applicants respectfully submit that claims 32-35, 38-40, 42-45 and 57 are patentable under 35 U.S.C. 112, second paragraph, and request that the rejection of such claims thereunder be withdrawn.

Claims 32, 33, 44 and 57 are rejected under 35 U.S.C. 102(a,e) over Redding et al (US 6,110,501). Applicants respectfully traverse.

Initially, Applicants note the amendment to claim 1 indicating that the waxes used in the invention are polymeric. The amendment is made for clarification only and literal

support is found throughout the specification. Redding discloses microcapsules for use in tablets. The microcapsules are seeded to increase the physical strength of the shell. The shell "may" include a coating comprising a vegetable-derived wax (Col. 4, ll 19-47). Applicants respectfully submit that the vegetable-derived waxes disclosed by Redding are not a polymeric wax that is the reaction product of a polybasic acid or derivative thereof, a fatty acid and a polyol, as claimed by Applicants. In fact, Applicants respectfully submit that waxes disclosed by Redding are not polymers. Accordingly, Applicants respectfully submit that claims 32, 33, 44 and 57 are patentable over Redding and requests that the rejection of the claims in view of Redding be withdrawn.

Claims 32, 33, 35, 38, 44, 48 and 57 are rejected under 35 U.S.C. 102(b) over Fues et al (US 5,308,623). Applicants respectfully traverse.

Fues discloses resorbable bone waxes that are prepared from oligomers of glycolic acid and/or lactic acid. Monofunctional and/or difunctional polyols are used to regulate molecular weight of oligomers (Col. 4, ll 61-65). Therefore, they are present only on a terminal end of the oligomer and thus are not included in the oligomeric backbone. Applicants respectfully submits that Fues fails to disclose anywhere the reaction of polybasic acids or derivatives thereof with a fatty acid and a polyol to prepare polymeric waxes for use in compositions as claimed by Applicants. Accordingly, Applicants respectfully submit that Fues cannot anticipate any of Applicants claims and respectfully requests that the rejections over Fues be withdrawn.

Claims 32-35, 38, 40, 42, 44 and 57 are rejected under 35 U.S.C. 102(b) over Iyengar et al (US 5,360,626). Applicants respectfully traverse.

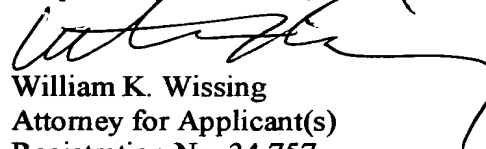
Iyengar discloses gelled, texturized oils and emulsions having properties similar to butter, margarine or hydrogenated vegetable oils, i.e. food products (Abstract). Polymeric, fat-soluble materials are used for the modification of the physical properties of fats and oils (Col 2, ll 5-14). Applicants respectfully submit that Iyengar fails to disclose or suggest the use of therapeutically effective amounts of therapeutic agents in combination with polymeric waxes as claimed by Applicants.

The Office Action states, "Bioactives incorporated include naturally derived proteins, milks-solids antidiuretics, salt (example 1)." Applicants respectfully disagree. As indicated in Example 1 and other examples, emulsions were prepared utilizing an

aqueous phase that included salts, gelling agent, milk solids and flavors (Col. 8, ll 1-24). Applicants respectfully submit that there is no disclosure or suggestion for the use of therapeutically effective amounts of therapeutic agents. Gelatin is used as a gelling agent. Milk solids are not therapeutic agents as that term would be construed by Applicants specification. Salt is used at a concentration of 1 percent by weight. Applicants respectfully submit that at that concentration, salt could not provide any diuretic effect, i.e. therapeutic effect, as apparently maintained by the Examiner. In fact, if the Examiner's assertion was correct, butter and margarine would be regulated by the Food and Drug Administration as a pharmaceutical product, not as a food product. Applicants respectfully submit that this is compelling evidence in favor of Applicants position. Accordingly, Applicants respectfully submit that claims 32-35, 38, 40, 42, 44 and 57 are patentable over Iyengar and request that the rejections in view thereof be withdrawn.

Based on all of the foregoing Applicants respectfully submit that all pending claims are patentable and earnestly request a notice of allowance to that affect. Applicants further submit that if the pending claims are determined to be patentable by the Examiner, claims 46 and 47, as well claims 36, 37 and 41 should the Examiner decide that these claims are finally withdrawn from consideration, also would be patentable and request that those claims also be allowed.

Respectfully submitted,



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